

are described in § 314.70(b)(3) and (c)(2)(i) through (c)(2)(iv) of this chapter. Authority to approve supplements that require in vivo bioavailability studies or in vivo study waiver requests is not included in this paragraph.

(f) The following officials are authorized to perform all functions of the Commissioner of Food and Drugs with respect to approval of supplemental applications to new drug applications for drugs for human use that are described in § 314.70(b)(1), (b)(2)(ii) through (b)(2)(x), (c)(1), and (c)(3) of this chapter. Authority to approve supplements that require in vivo bioavailability information or that require a change in the labeling of the drug, except changes that reflect only the use of a different facility or establishment, are not included in this paragraph. The supplemental applications to which this authorization applies may continue to be acted upon by the officials so authorized in § 5.10(a) and paragraphs (a) and (b) of this section.

(1) The supervisory chemists in the divisions in the Office of Drug Evaluation I, CDER.

(2) The supervisory chemists in the divisions in the Office of Drug Evaluation II, CDER.

[49 FR 14935, Apr. 16, 1984, as amended at 50 FR 30697, July 29, 1985; 50 FR 47207, Nov. 15, 1985; 52 FR 37764, Oct. 9, 1987; 54 FR 8319, Feb. 28, 1989; 55 FR 6247, Feb. 22, 1990; 55 FR 51688, Dec. 17, 1990; 57 FR 17980, Apr. 28, 1992; 58 FR 17094, Apr. 1, 1993; 59 FR 33431, June 29, 1994; 60 FR 57338, Nov. 15, 1995]

§ 5.81 Responses to Drug Enforcement Administration temporary scheduling notices.

The Associate Commissioner for Health Affairs is authorized to provide responses to the Drug Enforcement Administration's temporary scheduling notices under the Controlled Substances Act, as amended (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. 811(h)(4), as amended hereafter). The delegation excludes the authority to submit reports to Congress.

[60 FR 54424, Oct. 24, 1995]

§ 5.82 Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements.

(a) The Director and Deputy Director, Center for Drug Evaluation and Research, are authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto on drugs for human use, except for those drugs listed in § 314.440(b) of this chapter, that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act and subpart B of part 314 of this chapter and to issue notices refusing approval or withdrawing approval when opportunity for hearing has been waived.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research, for those drugs listed in § 314.440(b) of this chapter, are authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto on drugs for human use that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act and subpart B of part 314 of this chapter and to issue notices refusing approval or withdrawing approval when opportunity for hearing has been waived.

[54 FR 8319, Feb. 28, 1989]

§ 5.83 Approval of new animal drug applications and their supplements.

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of new animal drug applications, and supplements thereto, for new animal drugs submitted pursuant to section 512 of the Federal Food, Drug, and Cosmetic Act (the act).

(b) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of supplemental applications to approved new animal drugs submitted pursuant to section 512 of the act:

(1) The Director, the Deputy Director for Human Food Safety and Consultative Services, and the Deputy Director for Therapeutic and Production Drug Review, Office of New Animal Drug Evaluation, CVM.

(2) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(c) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of supplemental applications to new animal drug applications that are described by § 514.8(a)(4)(iii), (iv), and (v), and (d)(3) of this chapter.

(1) The Director, Division of Chemistry, Office of New Animal Drug Evaluation, CVM.

(2) The Director, Division of Surveillance, Office of Surveillance and Compliance, CVM.

(d) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of applications for animal feeds containing new animal drugs:

(1) The Director and Deputy Director, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(2) The Chief, Petition Review and Medicated Feeds Branch, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(3) The Medicated Feeds Specialist, Petition Review and Medicated Feeds Branch, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

[49 FR 14937, Apr. 16, 1984, as amended at 50 FR 14094, Apr. 10, 1985; 53 FR 2225, Jan. 27, 1988; 53 FR 17186, May 16, 1988; 53 FR 40055, Oct. 13, 1988]

§ 5.84 Issuance of notices, proposals, and orders relating to new animal drugs and feeds bearing or containing new animal drugs.

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to:

(1) Issue notices of opportunity for a hearing on proposals to refuse approval or to withdraw approval of new animal drug applications, and supplements thereto, for drugs for animal use and feeds bearing or containing new animal

drugs, submitted pursuant to section 512 of the Federal Food, Drug, and Cosmetic Act;

(2) Issue notices refusing or withdrawing approval when opportunity for hearing has been waived; and

(3) Issue proposals and orders to revoke and amend regulations for new animal drugs for drugs for animal use and feeds bearing or containing new animal drugs, corresponding to said action on such applications.

(b) The Director and Deputy Director, CVM, are authorized to issue notices of availability of Public Master Files containing data acceptable for use in applications for new animal drugs for drugs for animal use and feeds bearing or containing new animal drugs.

[49 FR 17936, Apr. 26, 1984]

§ 5.85 Authority to ensure that mammography facilities meet quality standards.

(a) The following officials are authorized to issue, renew, and extend certificates to mammography facilities under section 354(c) of the Public Health Service Act (42 U.S.C. 263b):

(1) The Director and Deputy Director for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(2) The Director, Office of Health and Industry Programs, CDRH.

(3) The Director, Division of Mammography Quality and Radiation Programs, Office of Health and Industry Programs, CDRH.

(b) The following officials are authorized to accept an application for a certificate under section 354(d)(1) of the Public Health Service Act:

(1) The Director and Deputy Director for Regulations and Policy, CDRH.

(2) The Director, Office of Health and Industry Programs, CDRH.

(3) The Director, Division of Mammography Quality and Radiation Programs, Office of Health and Industry Programs, CDRH.

(c) The following officials are authorized to approve accreditation bodies to accredit mammography facilities under section 354(e)(1)(A) of the Public Health Service Act:

(1) The Director and Deputy Director for Regulations and Policy, CDRH.